

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Evaluation of intravenous Vitamin B6 administration in chemotherapy induced nausea and vomiting in children suffering from malignancy

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Evaluation of intravenous Vitamin B6 administration on chemotherapy induced nausea and vomiting in children suffering from malignancy

Last update: **2018-02-16, 1396/11/27**

Update count: **0**

Registration date

2018-02-16, 1396/11/27

Design

This study will be conducted as a triple-blind clinical trials in children with malignancy undergoing chemotherapy in Amir Kabir Hospital in Arak. A total of 100 patients undergoing chemotherapy due to malignancy are included in the study.

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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f.farokhi@arakmu.ac.ir

Settings and conduct

This study will be conducted as a triple-blind clinical trials in children with malignancy undergoing chemotherapy in Amir Kabir Hospital in Arak.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: over 2 years old; both gender; children with malignancy Exclusion criteria: Dissatisfaction to participate in the study

Expected recruitment start date

2017-03-10, 1395/12/20

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Intervention group: In intervention group, patients are provided by Granisteron, 3 milligram in 3 milliliter, intravenously, 30 minutes before chemotherapy and vitamin B6 100 mg in 2-5 year age group, 200 mg in 5-10 year age group and 300 mg in over 10 year age group, intravenously, 6 hours before chemotherapy. In next chemotherapy cycle in same patients, they are provided by Granisteron, 3 milligram in 3 milliliter, intravenously, 30 minutes before chemotherapy and normal saline every 6 hours before chemotherapy.

Scientific title

Evaluation of intravenous Vitamin B6 administration in chemotherapy induced nausea and vomiting in children suffering from malignancy

Main outcome variables

Nausea; vomiting

Public title

Effect of intravenous Vitamin B6 administration in

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N67**

Registration date: **2018-02-16, 1396/11/27**

chemotherapy induced nausea and vomiting

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

being at the age of 2 to 5 years both gender Children with malignancy

Exclusion criteria:

Dissatisfaction to participate in the study

Age

From 2 years old to 5 years old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: 100

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participant and Analyzer are blind.

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University Of Medical Sciences

Street address

Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3814957558

Approval date

2017-03-06, 1395/12/16

Ethics committee reference number

IR.ARAKMU.REC.1395.443

Health conditions studied

1

Description of health condition studied

chemotherapy in children

ICD-10 code

T80.810

ICD-10 code description

Extravasation of vesicant antineoplastic chemotherapy

Primary outcomes

1

Description

Nausea

Timepoint

From beginning to the end of the chemotherapy session

Method of measurement

questionnaire

2

Description

vomitting

Timepoint

From beginning to the end of the chemotherapy session

Method of measurement

questionnaire

3

Description

Severity of nausea and vomiting

Timepoint

From beginning to the end of the chemotherapy session

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In intervention group, patients are provided by Granisteron, 3 milligram in 3 milliliter, intravenously, 30 minutes before chemotherapy and vitamin B6 100 mg in 2-5 year age group, 200 mg in 5-10 year age group and 300 mg in over 10 year age group, intravenously, 6 hours before chemotherapy. In next chemotherapy cycle in same patients, they are provided by Granisteron, 3 milligram in 3 milliliter, intravenously, 30 minutes before chemotherapy and normal saline every 6 hours before chemotherapy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Dr Noshin Sajadi

Street address

Amirkabir hospital, Parastar square

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sajadi@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Aliarash Anoshirvani

Street address

Vice chancellor for research, Payambar Azam

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anoshirvani@arakmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Aziz Eghbali

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr noshin Sajadi

Position

Assistant of professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Arefeh Adelnia

Position

دانشجوی پزشکی

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish relevant article in a journal.

When the data will become available and for how long

After publishing the article

To whom data/document is available

researchers who work at university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Sajadi

What processes are involved for a request to access data/document

They have to send their request to the professor who is the chair of the work and they also must pass administrative process of the university.

Comments